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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,296	10/16/2003	John T. Kilcoyne	1065-012US03	7920

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
04/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,296	KILCOYNE ET AL.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12-16 and 55-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12-16,55-57 and 59-69* is/are rejected.

7)☒ Claim(s) *58 and 70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 10, 12, 13, 15, 56, 57, 59, 60, and 65-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills (US Patent 5080663).

Regarding claim 10, Mills discloses a device comprising a housing with a tissue attachment surface (element 2) located within a concavity in the housing (element 6); a securing surface for securing the device that, when retracted, allows the tissue attachment surface to be brought into contact with tissue, and moves to an extended position through the tissue (elements 42, 44, 46, 48); and a physiological parameter detector that is within the housing (element 38; column 2, lines 57-61).

Regarding claim 12, Mills further discloses the securing structure being bioabsorbable (column 3, lines 8-10).

Regarding claim 13, Mills further discloses a vacuum lumen for drawing tissue into the concavity (column 2, lines 19-30).

Regarding claim 15, Mills further discloses an RF transmitter (column 1, line 19).

Regarding claim 56, Mills further discloses the securing structure extending at least part way across the concavity when extended (figures 6, 7).

Regarding claim 57, Mills further discloses a distal end of the securing structure (element 46) and a blind end in the concavity that can receive the distal end of the

securing structure when it is extended (the section labeled as 74 in figure 5, since extending the tag through the skin takes place with needle 26, and both the distal end 46 and the needle 26 remain in the far side of the needle channel – labeled as 74 – when extended, until the needle is retracted).

Regarding claims 59 and 60, Mills further discloses a wall of the housing being transparent so that the interior of the cavity may be viewed (column 2, lines 8-11).

Regarding claim 65, Mills discloses a device comprising a housing (element 2) with a tissue attachment surface inside a concavity (element 6); a securing structure for securing the device (elements 42, 44, 46, 48); a lumen in connection with the concavity for connection to a vacuum to draw tissue into the concavity (column 2, lines 19-30), and a physiological parameter detector that is within the housing (element 38; column 2, lines 57-61).

Regarding claim 66, Mills further discloses that the securing structure, when retracted, allows the tissue attachment surface to contact the tissue, and moves to an extended position through the tissue (figures 6, 7). Though Mills refers to the attachment structure as a "tag", the structure is equivalent to the broadest definition of the claimed term "pin" and as such, anticipates the claim.

Regarding claim 67, Mills further discloses the securing structure being bioabsorbable (column 3, lines 8-10).

Regarding claim 68, Mills further discloses the securing structure extending at least part way across the concavity when extended (figures 6, 7).

Regarding claim 69, Mills further discloses a distal end of the securing structure (element 46) and a blind end in the concavity that can receive the distal end of the securing structure when it is extended (the section labeled as 74 in figure 5, since extending the tag through the skin takes place with needle 26, and both the distal end 46 and the needle 26 remain in the far side of the needle channel – labeled as 74 – when extended, until the needle is retracted).

Claim Rejections - 35 USC § 103

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Murata (US Patent 3682160).

Regarding claim 14, Mills discloses all the elements of the claimed invention, as described above, except for the parameter detector comprising a pH detector. Murata teaches an implantable probe comprising a pH detector (column 6, lines 63-67; column 7, lines 5-64), in order to measure an internal pH value. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Mills with a pH detector, as taught by Murata, in order to measure an internal pH value.

4. Claims 16, 55, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Brockway (US Patent 6409674).

Regarding claim 16, Mills discloses all the elements of the claimed invention, as described above, except for an electrical contact that contacts bodily tissue and

transmits parameter data through the tissue. Brockway teaches an implantable probe comprising an electrical contact for contacting tissue and transmitting data relating to the parameter through the tissue (column 10 line 51 to column 11 line 5), in order to analyze the data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mills with an electrical contact for transmitting data through tissue, as taught by Brockway, in order to analyze the data.

Regarding claim 55, Mills discloses all the elements of the claimed invention, as described above, except for the securing structure comprising a pin. Brockway teaches an implantable probe comprising a pin for securing the device, in order to minimize the size of the securing structure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mills with a pin for securing the device, as taught by Brockway, in order to minimize the size of the securing structure.

Regarding claims 62 and 63, Mills discloses all the elements of the claimed invention, as described above, except for the housing including a docking structure comprising a projection, lumen, and recess for removable attachment of the device to an introducing instrument. Brockway an implantable probe comprising a housing including a docking structure comprising a projection (described as a plunger – column 12, lines 11-12), a lumen (element 640), and a recess (described as a cavity – column 12, lines 8-10) that permits removable attachment of the monitoring device to an instrument that introduces the monitoring device to the preselected attachment site (column 11 line 65 to column 12 line 10), in order to easily insert the device. It would

have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Mills with a docking structure, as taught by Brockway, in order to easily insert the device.

5. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Bombeck (US Patent 4981470).

Mills discloses all the elements of the claimed invention, as disclosed above, except for the device's predetermined attachment site comprising the esophagus, though Mills does disclose attaching the device in the patient's stomach via the esophagus (column 3 line 67 to column 4 line 1). Bombeck teaches an implantable monitoring device that may be attached to a patient's esophagus (column 3, lines 21-29), in order to monitor conditions in that vicinity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached Mills' device in a patient's esophagus, as taught by Bombeck, in order to monitor conditions in that vicinity.

6. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills in view of Brockway, and further in view of Bombeck.

Mills in view of Brockway discloses all the elements of the claimed invention, as disclosed above, except for the pH detector comprising an antimony electrode. Bombeck teaches a pH sensor comprising an antimony electrode (column 4 lines 51-65). It would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the invention of Mills in view of Brockway to include an antimony electrode similar to that of Bombeck, IV in to diagnose gastroesophageal reflux (column 2 lines 46-57).

Allowable Subject Matter

7. Claims 58 and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of claims 58 and 70, including, *inter-alia*, the blind end of the monitoring device's concavity having a locking structure for retaining the securing structure in its extended position.

Response to Arguments

8. Applicant's arguments filed 7 January 2008 have been fully considered but they are not persuasive.

Applicant's arguments regarding Brockway are moot in view of the newly amended claims.

Regarding Applicant's argument that Mills' sensor and housing are two separate devices, the Examiner disagrees. Though the two components of the device may be separated, they are initially, especially during attachment, connected as a single unit.

The rejections stand as FINAL.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735